

Appl. No. 10/151,350  
Reply to Office Action of November 18, 2003

### REMARKS/ARGUMENTS

This responds to the Office Action dated November 18, 2004. Applicant thanks the Examiner for providing helpful suggestions during the personal interview held on March 3, 2004.

In the Office Action, the following objections/rejections were stated:

- Claim 160 was withdrawn from consideration as being directed to a non-elected species.
- The disclosure was objected to on grounds of certain received inconsistencies and for failing to provide "antecedent basis" for the word "pusher."
- The drawings were objected to for failing to show certain devices recited in Claims 161 and 162.
- Claim 148 was rejected under 35 U.S.C. §112 on grounds that there was a lack of antecedent basis for "the third catheter."
- Claims 147, 156-159, 161 and 162 were rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 4,512,338 (Balko et al.) in view of United States Patent No. 5,122,136 (Guglielmi et al.).
- Claims 148-155 were rejected under 35 U.S.C. §103(a) as being unpatentable over Balko et al. in view of Guglielmi et al. and further in view of Massoud, Tarik F., Turjman, Francis, Ji, Cheng, Vinuela, Fernando, Gugliemi, Guido, Gobin, Y. Pierre, AND Duckwiler Gary R., *ENDOVASCULAR TREATMENT OF FUSIFORM ANEURYSMS WITH STENTS AND COILS: TECHNICAL FEASIBILITY IN A SWINE MODEL*, Am J Neuroradiol, 16:1953-1963, November 1995.
- Claims 147, 156 and 159 were rejected under either 35 U.S.C. §102(e) or §103(a) as being anticipated by or obvious over United States Patent No. 5,476,505 (Limone).
- Claims 148-155 were rejected under 35 U.S.C. §103(a) as being obvious over Limon in view of Massoud et al.

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By the foregoing amendment, the specification has been amended to include reference to the claimed "advancer." The other objections to the specification and drawings have been overcome by amendment of the claims to obviate the stated grounds for such objections.

Also, by the foregoing amendment, claims 149, 157, 160 and 161 have been cancelled and claims 147, 150, 151, 152, 153, 154, 155, 156, 158 and 162 have been amended.

Additionally, by the foregoing amendment, new dependent claims 163-165 have been added.

Thus, following entry of the foregoing amendment, claims 147-148, 150-156, 158-159 and 162-165 will be pending. As discussed herebelow, all of these claims, as amended, are believed to be in condition for allowance over all prior art of record.

Enclosed along with this response is the Declaration of Jay Alan Lenker, Ph.D. Pursuant to 37 C.F.R. §1.132. Dr. Lenker, an engineer having over 25 years of experience in the medical device industry, states that a) the claimed invention is not obvious over the cited prior art references, b) as of June 21, 1996 (the date on which the present patent application was filed) no volitionally detachable stent had been made available on the market or described in the literature and c) if the system recited in applicant's claims were to be made available on the market it would satisfy a long felt need by providing a system that could be used for embolization of cerebrovascular aneurysms with reduced potential for migration or protrusion of the embolic member (e.g., occlusion coil) from the aneurysm and into the true lumen of the blood vessel. Applicant respectfully requests that Dr. Lenker's declaration be considered, in conjunction with the remarks set forth herebelow, and deemed persuasive as to the novelty and non-obviousness of the presently claimed invention.

#### Method Claims 147-148 and 150-155 and 163-164

As stated by Dr. Lenker, the cited prior art references clearly do not describe or render obvious the method recited in independent claim 147. As the examiner will note, independent method claim 147, as presently amended, includes the steps of providing and positioning an embolus member within the vessel wall defect such that an intravascular member retains the embolus member within the vessel wall defect. Also, as presently amended, claim 147 requires that the intravascular member be in the form of an elongate strand when in its collapsed configuration and that such elongate strand assume a generally tubular shape (having a hollow flow channel therethrough) when the intravascular member is in its expanded configuration. Additionally, as now amended claim independent 147 requires that

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the releasable connection between the advancer and the intravascular member be volitionally releasable without requiring rotation of the advancer.

In contrast to the invention recited in independent claim 147, Balko et al., Guglielmi et al. and Limone describe stents, but do not even mention or suggest the use of their stents in conjunction with any implantable embolus member such that the stent would retain an embolus member within a vessel wall defect.

Massoud et al. does describe the use of a stent to retain an occlusion coil within an aneurysm, but the stent described by Massoud et al. is not releasably attached to an advancer as recited in amended claim 147.

Indeed, none of the stents described by Massoud et al., Balko et al., Guglielmi et al. or Limone are volitionally detachable from any advancer without requiring rotation of the advancer, as required by amended claim 147. In this regard, the Examiner has previously recognized that neither Massoud et al., nor Balko et al. nor Guglielmi et al. describe or suggest any attachment (releasable or otherwise) to an advancer or to the delivery catheter. However, in the Office Action, the Examiner did take the position that Limone et al. describes a stent that is connected to an advancer by way of a releasable connection. In response to this, Applicant respectfully points out that Limone merely describes a helical coil stent 10 that is deployed by rotating advancer shafts 32 and 34. Limone's stent has ends 12, 14 that are inserted into slots 42, 44 on the advancer shafts 32, 34. When Limone's stent 10 expands, the "stent ends 12 and 14 are either completely released from slots 42 and 44, or are loosely held within the slots." (See, Col. 4, Lines 57-60) Thus, the ends of Limone's stent may become released from the slots simply as a result of routine expansion of the stent, without any volitional or purposeful detachment step being performed by the operator. Moreover, Limone does not describe or suggest any manner in which the stent could be retrieved back into the catheter after the stent has been expanded. As explained during the interview held on March 3, 2004, the releasable connection of Applicant's intravascular member to the advancer provides the distinct advantage of enabling Applicant's intravascular member to be retracted back into the delivery catheter any time until the releasable connection has been volitionally released by the operator (see new dependent claims 163 and 164). Thus, the method recited in amended independent claim 147 is patentably distinguishable over all prior art of record including Balko et al., Guglielmi et al., Limone and Massoud et al.

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Dependent claims 148 and 150-155 and 163-164 further define or further limit the subject matter of independent claim 147 and, thus, are also distinguishable over the prior art for at least the same reasons as claim 147.

**System Claims 156, 158-159, 162 and 165**

Independent system claim 156, as presently amended, recites a system that comprises an intravascular member and an embolic member, wherein the intravascular member has a) a collapsed configuration wherein it is in the form of an elongate strand member that is positionable within the delivery catheter and b) an expanded configuration wherein the elongate strand member assumes a generally tubular shape that defines a hollow flow channel therethrough. Additionally, amended independent claim 156 recites that the intravascular member is attached to the advancer by a releasable connection that is volitionally releasable without requiring rotation of the advancer. Also, amended claim 156 recites that the embolic member is implantable within an aneurysm or other defect such that it will prevent the embolic member from escaping from the aneurysm or other defect and into the true lumen of the blood vessel.

As explained above, of the four (4) references cited in the Office Action, only Massoud et al. describes the use of an intravascular member (e.g., a stent) in combination with an embolic member such that the stent will prevent the embolic member from escaping from an aneurysm. However, the stent described by Massoud et al. is not attached to any advancer by way of a releasable attachment and no method is described for retraction of Massoud's stent back to its collapsed configuration on or in the delivery catheter once it has been expanded within the blood vessel. Thus, for the same reasons stated hereabove with respect to method claim 147, the system recited in independent claim 156 is distinguishable, not only from Massoud et al., but also from Balko et al., Guglielmi et al. and/or Limone, alone or in combination with each other.

Dependent claims 158-159, 162 and 165 further define or further limit the subject matter of independent claim 156 and, accordingly, are distinguishable over the prior art for at least the same reasons as stated above with respect to claim 156.

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**Conclusion**

All claims 147-148, 150-156, 158-159 and 162-165 are believed to be in condition for allowance. Issuance of a Notice of Allowance is earnestly solicited.

Respectfully submitted,  
STOUT, UXA, BUYAN & MULLINS, LLP

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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being transmitted via facsimile to the United States Postal Service at 703-872-9306 to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 19, 2004.

Dated: April 19, 2004

By:



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